

## REMARKS/ARGUMENTS


Entry of the foregoing amendments is respectfully requested prior to fee calculation. The amendments are intended to place the application in better condition for examination. Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of the application, he is invited to contact Applicants' representative at the number indicated below.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02089US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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**Version With Markings to Show Changes Made**

[0008] Plate haptic lenses are sometimes desirable because they provide certain advantages over long loop lenses, including stabilization of the vitreous with substantially less probability of the most serious complications of cataract surgery, these being retinal detachment and cystoid macular edema. Another advantage is the consistent posterior location of the optic, which not only stabilizes the vitreous, but provides more predictable post-operative, uncorrected visual acuity. A further advantage is that the posterior location of the lens results in tight contact of the lens with the posterior capsule, thereby resulting in reduced rate of [specification] opacification of the posterior capsule with resultant reduced posterior capsulotomy rate.

[0011] After implantation of the accommodating intraocular lens in the capsular bag, active ectodermal cells on the posterior surface of the anterior capsule rim of the bag cause fusion of the rim to the elastic posterior capsule of the bag by fibrosis about the lens extended portions in such a way that these portions are effectively “shrink-wrapped” by the fibrous tissue so as to form radial pockets or tunnels in the fibrous tissue which contain the haptic portions with their distal ends positioned within the cul-de-sac of the capsular bag. The lens is thereby fixated within the capsular bag with the lens optic aligned with the opening in the anterior capsule bag. The anterior capsule rim shrinks during fibrosis, and this, combined with fibrosis about the extended portions, causes some radial compression of the lens so as to tend to move the optic relative to the outer ends of the extended portions [in one director or the other] posteriorly along the optic axis. The fibrosed, leather-like anterior capsule rim prevents anterior movement of the optic and urges it rearwardly during fibrosis. Accordingly, fibrosis induced movement of the optic occurs posteriorly to a distant vision position wherein either or both the optic and the inner ends of the extended portions press rearwardly against and stretch the elastic posterior capsule rearwardly.

[0012] During surgery, the ciliary muscle of the eye is paralyzed with a ciliary muscle relaxant, i.e., a cycloplegic, such as atropine, to place the muscle in its relaxed state. Following surgery, a ciliary muscle relaxant is periodically introduced throughout [a] the post-operative fibrosis [and] healing period for as long [(such] as two days and up to three weeks[])] to maintain the ciliary muscle in its relaxed state until fibrosis is complete. This drug-induced relaxation of the ciliary muscle prevents contraction of the ciliary muscle and [thereof and] therefore immobilizes the capsular bag. By this means, the lens optic is fixed

during fibrosis in its distant vision position within the eye relative to the retina and the lens presses rearwardly against and thereby posteriorly stretches the elastic posterior capsule of the capsular bag. If the ciliary muscle was not thus maintained in its relaxed state until the completion of fibrosis, the ciliary muscle would undergo [essentially] normal brain-induced [vision accommodation] contraction and relaxation during fibrosis, and the intraocular lens would not necessarily fix in the distant position but in some other location along the axis of the eye.

[0013] The present invention provides haptic lens features which serve to fixate the distal haptic portions of the lens, thus preventing dislocation and slipping from the proper positions in pockets or tunnels formed over the haptic lens features by fibrosis. Enlarged and/or distal haptic portions or protuberances are prevented by their larger dimension from moving or sliding along pockets or tunnels formed by fibrosis about proximally inward haptic portions. The enlarged distal structural features prevent the haptic from sliding inwardly relative to such fibrosis pockets to fixate and prevent dislocation of the intraocular lens. The enlarged distal structural features may take such forms as: protuberances extending from one or both sides of distal portions of plate haptics; flexible extensions extending from distal corners of lens plate haptics, which extensions may have protuberances; protuberances extending outwardly from spring loops or filamentary loops; enlarged end portions or protuberances on distal portions of a plurality of haptics extending from their proximal ends at an optic or plate haptic; enlarged wide distal portions of haptics tapered to widen in the distal direction; prong protuberances extending laterally outwardly from distal portions of haptics; and notches in side edges of distal portions of haptics.

[0014] Other preferred embodiments of the invention include extended or distal protuberances and/or knobs and or openings defined in distal portions of haptics, which serve to fixate the distal haptic portions in the periphery of the capsular bag between the posterior bag and the anterior capsule remnant by the fibrosis process described in the foregoing Background of the Invention, by the prevention of relative movement of the distal portions of the haptics relative to pockets or tunnels formed by fibrosis about proximally inward haptic portions. Other preferred embodiments also include flexible loop haptics extending from disk haptic portions, knobs provided in the distal portions of a disk haptic element and/or, openings provided in the distal portions of a disk haptic element, and knobs and/or openings provided in the distal portions of a plurality of plate-type haptics extending from the optic to their distal edge portions.

[0015] Figure 1 is an elevation view of a preferred embodiment of the invention, showing a plate haptic lens with enlarged protuberances at its distal [corners] edge;

[0017] Figure 3 is an elevational view of an embodiment of the invention wherein flexible extensions with protuberances extend diagonally outwardly from distal [corners] edges of haptic plates;

[0024] Figure 7 is an elevational view of an embodiment of the invention wherein are shown in partial views two forms of [prong] protuberances extending laterally outwardly from [distal] portions of oppositely extending haptics;

[0028] Figures 10 and 11 are related embodiments having plate-type haptics extending in the directions from an optic, and having extending therefrom step portions. [from which extend or are] These step portion may have mounted knobs or protuberances extending from their surfaces.

[0029] Figures 12 to 14 illustrate an embodiment [an embodiment] wherein flexible or filament type loop haptics extend oppositely from an optic and having at the end of each a knob or protuberance, Figures 13 and 14 showing the correct manner of engagement of the loop end portion and knob in the cul-de-sac of the capsular bag for peripheral fixation in the juncture of the posterior capsule and the anterior capsular remnant by fibrosis, and Figure 14 showing an incorrect engagement of an improperly designed end portion of the loop haptic;

[0046] With relatively constant movement of lens haptics relative to the [on] optics, there can be disengagement of distal haptic portions relative to the bag periphery between the posterior bag and anterior remnant, if adequate retention is not provided. Such disengagement of continued operational force can result if adequate fixation is not provided, and can result [form] from such factors as capsular bag shrinkage during fibrosis causing a tear to occur in the capsular bag, thus possibly resulting in lens dislocation and the haptic being then positioned in the vitreous in the posterior portion of the eye, with serious complications.

[0052] Figure 6 illustrates an embodiment 50, [which is not an accommodation lens,] wherein each of plate haptics 52 has a wider distal protuberance portions 54 than proximally adjacent haptic portions. Distal protuberance portions of the haptics are defined by tapered haptic configurations which widen in the distal direction. The wider distal haptic portion

prevents movement of the haptic toward the optic being retained against movement relative to the pocket defined by fibrosis about the plate haptic inwardly of the distal portion.

[0053] Figure 7 illustrates another embodiment 50 of the invention wherein [prong] protuberances 62, with [prongs 64 with] rounded ends 64, extend laterally outwardly from distal portions of plate haptics extending from an optic 66. The [prong] protuberances 62 effectively prevent proximal movement toward optic 66 by inward portions of the haptics relative to the fibrosis pockets formed about proximally inward portions of the haptics.

[0059] Figures 12-14 illustrate embodiments wherein flexible or filamentary loop haptics 104, 106 of generally arcuate configuration extend oppositely from an optic 108. Each loop haptic has at its end a knob or protuberance 110 somewhat similar to that shown in Figure 8A. The loop haptics extend into the periphery of the bag between the anterior remnant and the posterior capsule to fixate the haptics and prevent movement of the knobs through fibrosis-defined tunnels defined about the loops. Figures 13 and 14 illustrate respectively the correct manner for the loop haptic to be oriented to engage the bag periphery wherein a portion of the loop and the knob engage the bag periphery. Figure 14 shows an undesirable disposition of the loop haptic and knob in the [fibrosis] fibrosed capsule which does not provide optimum and desirable engagement with the bag periphery.